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APPLICATION NO. \	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/762,963	01/22/2004	Terri K. Taylor	022719-0052	6349
21125 7590 11/02/2007 NUTTER MCCLENNEN & FISH LLP WORLD TRADE CENTER WEST 155 SEAPORT BOULEVARD BOSTON, MA 02210-2604			EXAMINER RAMIREZ, JOHN FERNANDO	
			ART UNIT 3737	PAPER NUMBER
			NOTIFICATION DATE 11/02/2007	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docket@nutter.com

Office Action Summary	Application No. 10/762,963	Applicant(s) TAYLOR ET AL.	
	Examiner John F. Ramirez	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 1-19, 26, 35 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-25, 27-34 and 36-40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Claims 1-10, 12-19 and 41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on July 17, 2007.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 20-25, 27-34 and 36-40 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

On October 26, 2005, the USPTO published Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility. See:

(<http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/guidelines101_20051026.pdf>).

This guidelines details a procedure for determining patent eligible subject matter. As to claims 1 and 36, the first step in this process is whether the claims fall within one of enumerated categories. In the immediate application, the claims are drawn to a device/system- an "Acoustic monitoring device for verifying the pressure setting of a valve mechanism in an implantable device" - and meets this step. However, the analysis does not end here. The next step is whether a judicial exception (abstract ideas, laws of nature, natural phenomenon) is provided in the claim. In the immediate

application, claims 20 and 37 clearly include one of the judicial exceptions in that “a transmitter configured to generate an energy field sufficient to cause movement of the valve mechanism; and an acoustic sensor electrically coupled to the transmitter **for detecting any acoustic signals** generated by the valve mechanism during an adjustment cycle; wherein the transmitter communicates **the detected acoustic signal to the device for analysis**” are nothing more than abstract ideas.

While abstract ideas alone are not eligible, the claim as a whole must be analyzed to determine whether it is for a particular application of the abstract idea. For claims including such excluded subject matter to be eligible, the claim must be for a practical application of the abstract idea, law of nature, or natural phenomena. To satisfy the requirement of a practical application, the claimed invention must:

(1) transform an article or physical object to a different state or thing; if no transformation, then

(2) the claimed invention must produce a useful, concrete, and tangible result.

Regarding (1) above, the claims do not provide a transformation or reduction of an article to a different state or thing. Grouping equivalent dipoles based on predetermined criterion and solving inverse problems clearly do not transform an article or physical object to a different state or thing. Accordingly, one must then consider whether the claimed invention produces a useful, concrete, and tangible result.

(1) Useful Result

For an invention to be “useful” it must satisfy the utility requirement of section 101. The USPTO's official interpretation of the utility requirement provides that the

utility of the invention has to be (i) specific, (ii) substantial and (iii) credible. See MPEP 2107. It can be argued that the claim does not provide a useful result in that the claim does not actually solve a problem. It does not appear to be specific as to how the problem is solved and, if solved, it is not specific as to the use of this solution.

(2) Tangible Result

The tangible requirement does not necessarily mean that a claim must either be tied to a particular machine or apparatus or must operate to change articles or materials to a different state or thing. However, the tangible requirement does require that the claim must recite more than a 101 judicial exception, in that the process claim must set forth a practical application of that 101 judicial exception to produce a real world result.

Regarding the tangible result requirement, the claim clearly does not provide a practical application. The problem, even if solved, is not practically applied to produce a real world result. For example, once the problem is solved, how is this then applied?

(3) Concrete Result

Another consideration is whether the invention produces a "concrete" result. Usually, this question arises when a result cannot be assured. In other words, the process must have a result that can be substantially repeatable or the process must substantially produce the same result again. Resolving this question is dependent on the level of skill in the art. For example, if the claimed invention is for a process which requires a particular skill, to determine whether the process is substantially repeatable will necessarily require a determination of the level of skill of the ordinary skilled artisan.

Regarding the concrete result requirement, the claim does not provide a result

Art Unit: 3737

that can be assured in that the result can not be substantially repeatable and the process can not substantially produce the same result again.

In view of the above analysis, applicant's **claims 20 and 37** are a device/system, which includes a judicial exception therein. Upon review of the claims as a whole, there is no transformation nor do the claims produce a useful, concrete, and tangible result. Accordingly, the claims are non-statutory.

In relation to **claims 21-25, 27-34, 36 and 38-40** depend from claims 20 and 37 respectively, and as such, include the various limitations thereof. As discussed above, claims 20 and 37 are a device/system that provides no physical transformation and there is no practical application, which is useful, concrete and tangible.

Claims 20-25, 27-34 and 36-40 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

In relation to **claims 20 and 37**, do not provide a useful result in that the claims do not actually solve a problem. It does not appear to be specific as to how the problem is solved and, if solved, it is not specific as to the use of this solution.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-25, 27-34 and 36-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Art Unit: 3737

In claims 20 and 37, it is unclear as to how is generated the energy field sufficient to effect movement of the valve mechanism of the implantable device. Therefore, it is also unclear as to how is detected the acoustic signals generated by the valve mechanism.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 20-25, 27-34 and 36-40 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-29 of U.S. Patent No. 6,685,638. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in the present application involve an obvious alternate variation of the claims in the cited patent reference.

Furthermore, the subject matter claimed in the instant application is fully disclosed in the referenced patent and would be covered by any patent granted on that patent reference since the referenced patent and the instant application are claiming common subject matter.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John F. Ramirez whose telephone number is (571) 272-8685. The examiner can normally be reached on (Mon-Fri) 7:00 - 3:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JFR


Brian L. Casler
Supervisor
Art Unit 3737